IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

GE HEALTHCARE BIO-SCIENCES AB, GE HEALTHCARE BIO-SCIENCES CORPORATION, and GENERAL ELECTRIC COMPANY, Plaintiffs, v. BIO-RAD LABORATORIES, INC., Defendant and Counterclaim Plaintiff.	Civil Action No. 1:14-cv-07080-LTS **ORAL ARGUMENT REQUESTED**

BIO-RAD LABORATORIES, INC.'S OPPOSITION
TO GE'S MOTION FOR A PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

INTRODUCTION

GE's motion for preliminary injunction concerns alleged infringement of a single, very narrowly drawn patent relating to automated fluid handling systems. Ignoring the narrowness of its claims, Bio-Rad's long history of innovation in this area, and the prior art, GE reads its patent broadly and seeks to obtain through litigation what it cannot accomplish in the marketplace. GE's motion must be denied because GE is unlikely to succeed on the merits. Its patent is invalid and unenforceable, Bio-Rad does not infringe, and GE cannot prove irreparable harm. In addition, the balance of hardships and public interest factors favor Bio-Rad because an injunction would hurt consumer choice.

GE touts its invention as an automated, modular fluid handling system, in which fluidics are separated from electronics in each module by a panel, and the modules fit into the system housing such that all electronics are inside the housing. But GE did not invent automated fluid handling systems, or modules for such systems that fit into a housing. Furthermore, GE did not invent the concept of separating fluidics from electronics in each module and putting the electronics inside the housing. Each of these features was well-known long before GE filed the patent-in-suit in 2009.

Even if the patent-in-suit were valid, the NGC machine does not infringe. The NGC machine lacks at least two elements of the claims: (1) a modular panel that separates the electronics of each module from the fluidics; and (2) all the electronics internal to the system housing. Every Bio-Rad NGC module has electrical components, including at least a printed circuit board, electrical connectors, and LEDs, on the same side of the modular panel as the fluids, outside the system housing.

GE also fails to prove it will suffer irreparable harm. GE has provided no evidence that the patented features drive customer demand for Bio-Rad's NGC systems. [redacted]

[redacted] GE has similarly provided no evidence that the, at best, incremental advance in modularity claimed in the '718 patent drives customer demand. [redacted] GE's allegations of irreparable harm through lost sales, price erosion, and loss of goodwill and "first mover advantage" are similarly unsupported.

The balance of the hardships and the public interest also weigh against an injunction, particularly at this stage of litigation. Such a restriction on consumer choice would have negative social consequences because these systems are used for research and for developing treatments and cures for a variety of human diseases.

STATEMENT OF FACTS

I. The Touted Features of the '718 Patent, Modularity and Separation of Electronics and Fluidics, Were Well Known in the Prior Art

[redacted] GE claims that each system practices the patent-in-suit, U.S. Patent No. 8,821,718 ("the '718 patent"), and that one of the new aspects of these systems is

their modularity. (Opening Br. at 1, 7.) [redacted]

GE's attempt to rely on the novelty of separating fluidics from "non fluidics" (*e.g.*, electronics or electrical components) in its newer systems is similarly unavailing. [redacted] In fact, GE's failure to disclose its own prior art systems to the USPTO during prosecution of the patent-in-suit likely constituted inequitable conduct that renders the '718 patent unenforceable.

Furthermore, the Applikon 2040 system, which was available in 1999, 10 years before GE filed its patent, is an automated fluid handling system that utilizes modularity and a separation of electronics and fluidics, the very features that GE argued distinguished its invention from other prior art. In fact, the similarity between the Applikon ADI 2040 system and GE's subsequent AKTA Avant, which GE claims practices the '718 invention, is striking (*see* Figures below). As also shown in the figures below, the Bio-Rad NGC system, unlike both the prior art system and the AKTA Avant, however, contains LED lights, LED display screens, and other advanced electronics on the outside of the units to provide added convenience and ease of use to Bio-Rad customers.

		
Applikon ADI 2040 Prior Art System	AKTA Avant	Bio-Rad NGC

II. GE and Bio-Rad Have Competed in the Liquid Chromatography Business for Over a Decade

While GE's motion insinuates that Bio-Rad is a recent entrant to the liquid chromatography field, [redacted]

Instead of concentrating on the merits, *i.e.*, having its expert construe the claims and review the numerous narrowing statements the inventors made to obtain their patent, GE raises baseless and unfounded allegations in its complaint and in Dr. Darby's declaration that a former GE employee who joined Bio-Rad somehow improperly shared "insight[s] into the development and launch strategy of the AKTA modular protein purification systems" with Bio-Rad. (Darby Dec. at ¶ 16.) These allegations are unfounded and border on slanderous. GE's resort to such tactics merely serves to highlight the weakness of its infringement, validity, and enforceability case, as well as its lack of irreparable harm.

III. The '718 Patent-in-Suit Issued the Day GE Filed This Action

Notably, GE filed the complaint in this action the same day that the patent-in-suit issued, September 2, 2014. GE launched its AKTA Avant system in 2009, and the AKTA Pure system

in 2012. [redacted] GE's burden to show that a preliminary injunction is warranted in this case is therefore more difficult than usual. Harm such as lost sales, price erosion, loss of goodwill or "first mover advantage" that GE alleges it suffered before the issuance of the patent-in-suit cannot serve as the basis for injunctive relief. Moreover, GE's arguments that it has suffered a loss of "first mover advantage" or goodwill five years after it launched the AKTA Avant, and two years after it launched the AKTA Pure are implausible on their face.

STANDARDS FOR PRELIMINARY INJUNCTION

A preliminary injunction is a "drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). Plaintiffs seeking preliminary injunctive relief must establish that: (1) they are likely to succeed on the merits; (2) that they are likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of hardships tips in their favor; and (4) that an injunction is in the public interest. *Winter v. National Res. Def. Council, Inc*., 555 U.S. 7, 20 (2008). A preliminary injunction will not issue unless the movant establishes both of the first two factors. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). And to satisfy the irreparable harm factor, a patentee must establish that: (1) absent an injunction, it will suffer irreparable harm; and (2) a sufficiently strong causal nexus relates the alleged harm to the alleged infringement. *See Apple Inc. v. Samsung Electronics Co., Ltd.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). Here, GE fails to satisfy any of the four factors.

ARGUMENT

I. GE IS NOT LIKELY TO SUCCEED ON THE MERITS

The '718 patent claims a modular automated fluid handling system with the modules set into slots in a system housing. Each module is made up of, *inter alia*, a "fluidics section," "non

fluidics section," and a "panel member" arranged to "separate" the "fluidics section" from the "non fluidics section" such that the fluidics section of each module is external to the system housing and the non fluidics section of each module is internal to the system housing. (*See* '718 Patent, at 9:9-14). The "panel member" of each module attaches the module to the front of the system housing, referred to in the patent as the "liquid handling panel." (*Id.* at 5:26-29, 9:9-14.)

As described in detail in the declarations of Dr. Gale and Dr. Kinget, the Bio-Rad NGC system does not infringe the asserted claims because it lacks the fundamental separation of electronics and fluidics that GE repeatedly stressed during prosecution to distinguish its invention from the prior art. Further, if the claims are given the overbroad construction GE appears to be applying, to allow some electronics to be outside the housing and on the same side of the modular panel member as the fluidics,[1] then there is no doubt the prior art Applikon ADI 2040 machine invalidates the claims of the '718 patent.

A. GE Must Show a Likelihood That It Will Prove Infringement and That the Patent Claims Will Withstand Bio-Rad's Validity and Enforceability Challenges

For a patentee to establish that it is likely to succeed on the merits, it must demonstrate that it will likely prove infringement of one or more claims of the patent-in-suit, and that any challenges to validity or enforceability lack substantial merit. *See, e.g., Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343, 1348 (Fed. Cir. 2003). A preliminary injunction should not issue if an alleged infringer raises a substantial question regarding infringement, validity, or unenforceability. *See, e.g., Astra-Zeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010). In opposing a preliminary injunction, the defendant need not prove invalidity or unenforceability by clear and convincing evidence. *See, e.g., Altana Pharma AG v. Teva Pharm.*

[1] GE's expert never evaluated the NGC machine to determine whether it had electronics on the same side of the panel as the fluidics and outside the housing.

USA, Inc., 566 F.3d 999, 1006 (Fed. Cir. 2009). Once a defendant presents persuasive evidence of invalidity or unenforceability, the plaintiff must respond with contrary evidence. *See, e.g., Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009).

B. Claim Construction

Where likelihood of success depends on the meaning of disputed claim terms, the court may preliminarily construe the claims. *See, e.g., Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1220 (Fed. Cir. 1996). Claims are generally given their plain and ordinary meaning. *See, e.g., Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). In addition to the specification, the prosecution history is an important source of intrinsic evidence for claim construction, particularly where claim terms have been added by amendment. *See, e.g., Sunovion*, 731 F.3d at 1277; *Board of Regents of the University of Texas System v. BENQ America Corp.*, 533 F.3d 1362, 1369 (Fed. Cir. 2008). And where the claim language is clear and the plain meaning is supported by the prosecution history, courts may not rewrite claims to preserve operability or validity, even where the plain meaning excludes the sole embodiment disclosed in the patent. *See, e.g., Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1215-16 (Fed. Cir. 2008). Claims are construed from the perspective of the person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170, 126 S. Ct. 1332 (2006) (*en banc*).

Here, two limitations establish that there is no infringement: (1) the limitation that a modular panel member separates fluidics from non fluidics (electronics and electrical components) ('718 Patent, 9:6-9; 10:32-35); and (2) the limitation that component positions of the liquid housing panel are arranged for attachment of the modular panel members such that said "fluidics sections are external to the housing and said respective non fluidics sections are internal to the housing." ('718 Patent, at 9:10-14; 10:36-39) The plain language of these

elements requires separation of fluidics components from electronics by a modular panel, such that the fluidics components are outside the system housing and electronics are inside the system housing. ('718 Patent, 9:6-14; 10:32-39). Moreover, the prosecution history leaves no room to escape these requirements. To overcome multiple rejections over numerous prior art references, the applicants repeatedly amended their claims and distinguished the prior art on the grounds that the prior art did not disclose separation of fluidics from electronics, and did not disclose that all electronics were inside the system housing, separated from fluidics on the outside of the system housing.

Notably, GE's expert, Dr. Scandella, did not perform any claim construction as part of his opinion. (Ex. 5, 10/17/2014 Scandella Dep. Tr., at 125:9-14; 126:25-127-6.) Therefore, he did not review any of the statements GE made distinguishing the prior art on the basis that it lacked separation of fluidics from electrical parts as part of his claim construction analysis. (Ex. 5, 10/17/2014 Scandella Dep. Tr., at 126:10-14.) As a result, Dr. Scandella did not consider at all whether the NGC system had electronics, electrical components or control means on the same side of the panel member as the fluidics, or whether there were electronics outside the housing. (Ex. 5, 10/17/2014 Scandella Dep. Tr., at 134:6-135:14; 142:16-144:5; 149:11-150:23.) Because Dr. Scandella failed to perform a proper analysis, his opinion that the NGC system infringes the claims is not reliable and should be excluded. *See, e.g., MicroStrategy Inc. v. Business Objects, S.A.*, 429 F.3d 1344, 1356 (Fed. Cir. 2005).

1. The '718 Claims Require a Panel Member to Separate Fluidics from Electronics, and Electronics to Be Internal to the Housing

To overcome rejections over prior art, the applicants amended the claims to add the limitations to claims 1 and 16 of a modular panel member separating fluidics and electronics such that electronics are internal to the housing. (Ex. 6, '718 File History, at BRGE00000349

and 353.) The applicants then relied on these limitations to distinguish prior art on the grounds that in the prior art, "the fluidics and non fluidics (electronics etc) of the modules (fluid handling units) are not separated . . . as in presently claimed invention."[2] (Ex. 6, '718 File History, at BRGE00000358.) The applicants further distinguished this prior art reference on the grounds that the reference disclosed components such as a detector, "which is very likely to be electronic in nature and conductors which both appear to be next to liquid paths." (Ex. 6, '718 File History, at BRGE00000357.) In particular, the applicants pointed out that this prior art detector module "illustrates that fluid and electrical parts are adjacent, not on either side of a panel." (Ex. 6, '718 File History, at BRGE00000358.) Moreover, during prosecution, the applicants distinguished this reference on the grounds that the modules of the prior art system "do not separate their fluidics and electrical parts," but instead, in the prior art system, "the fluid and non fluidic parts are together." (Ex. 6, '718 File History, at BRGE00000358.)

Also during prosecution, the applicants distinguished prior art on the grounds that, in the prior art, "respective non fluidics sections are not internal to any housing as claimed," because in this reference, there were electrical connections external to the system housing. (Ex. 6, '718 File History, at BRGE00000434.) These statements are consistent with the plain meaning of the claims and confirm the requirement that all electronics and electrical components such as electrical connections must be internal to the system housing.

[redacted]

[2] It is unclear whether GE is asserting infringement under the doctrine of equivalents in its motion. In any event, this amendment bars application of the doctrine of equivalents to the limitations of a panel member separating fluidics from electronics, such that the electronics are internal to the housing. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734, 122 S. Ct. 1831 (2002). Moreover, at the preliminary injunction stage, it is rare for an injunction to issue based on doctrine of equivalents infringement allegations. *See, e.g., Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377, 1384 (Fed. Cir. 2000) (stating that the "highly factual inquiry" required for the doctrine of equivalents analysis "rarely comes clear on a premature record").

[redacted]

2. Electronics and Electrical Components

Because claims 1 and 16 define the "non fluidics section" as "comprising electronics, electrical components, or control means," and because the claims require the electronics to be internal to the housing, it is necessary to construe "electronics" and "electrical components." *See, e.g.*, *Sunovion*, 731 F.3d at 1276.

The plain meaning of electrical components and electronics includes electrical wires, electrical connections and contacts, and conductors. This plain meaning is fully supported by the specification and file history. (*See, e.g.*, '718 patent at 1:27-33; Ex. 6, '718 File History, at BRGE00000358, 429-30.) GE's expert, Dr. Scandella, admitted that the following components were electronics as used in the claims of the '718 patent: (1) conductivity cells; (2) light bulbs; (3) LEDs; (4) display screens; (5) printed circuit boards; (6) wires that conduct electricity; (7) buttons that the user presses that allows a certain action to occur; and (8) pressure transducers. (Ex. 5, 10/17/2014 Scandella Dep. Tr., at 19:17-23; 29:23-30:1-2; 34:13-36:22; 52:14-53:5; 62:1-17; 150:18-20.)

The identification of these components as electronics and electrical components is consistent with the applicants' arguments in the prosecution history. (Ex. 6, '718 File History, at BRGE00000357, 358, 429-30.) It is also consistent with the way that a person of ordinary skill in the art reading the patent and the prosecution history would understand the terms electronics and electrical components. (Kinget Decl., ¶¶ 32-47; Gale Decl., ¶¶ 168-71.) This plain meaning

is also consistent with standard electronics dictionaries from the relevant timeframe. (Kinget Decl., ¶ 32.)

C. The NGC Systems Do Not Infringe the '718 Patent

1. GE Misidentified the "panel member" in the NGC System

All the claims require an interchangeable module that has a "panel member arranged . . . for attachment of the modular component to a component position of the liquid handling panel," *i.e.*, the front of the system housing. The specification is fully consistent with this interpretation of the claim, and consistently describes the panel as the component of the module that attaches to the front of the system housing. (*See, e.g.*, '718 patent, Figures 2, 4, 5a and 5b.)

GE's expert Dr. Scandella did not disassemble any of the accused parts or do any detailed analysis to identify the "panel" in the accused Bio-Rad NGC machine. Instead, as shown below, he relied on a single picture from the NGC instrument guide as purportedly showing a front facing panel that he described as "provid[ing] for attachment of the modular component to the liquid handling panel." Dr. Scandella's identification of this outer overlay ("Overlay") as a modular panel that attaches to the liquid handling panel is incorrect. [redacted]

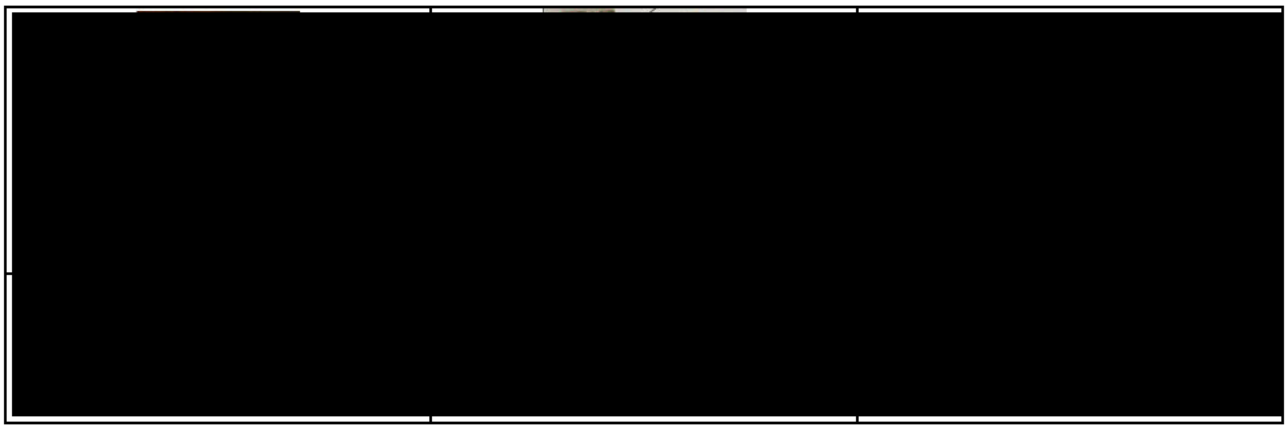
[redacted]

2. The NGC System Lacks "a panel member arranged to separate the fluidics section from the non fluidics section . . ."

In the Bio-Rad systems, [redacted] does not meet the claimed limitation of a "panel member arranged to separate the fluidics section from the non fluidics section" because every unit of the Bio-Rad NGC systems contains electronics or electrical components on the outside of the [redacted], on the same side of the [redacted] as the fluidics. For example, every Bio-Rad unit/module contains LEDs on the user side of the [redacted], on the outside of the unit, alongside the fluidics components as shown by the red arrow in the figure below on the left. (Gale Decl., ¶¶ 82, 85, 92, 95, 100, 106, 114, 122, 128, 131, 136; Kinget Decl., ¶¶ 46, 67, 83.)

[redacted] Dr. Scandella admitted that each of these are electronics or electrical components and Bio-Rad's experts agree. (Gale Decl., ¶¶ 168-69; Kinget Decl., ¶¶ 35-38.) [redacted] (Gale Decl., ¶¶ 81-82, 84-85, 91-92, 94-95, 99-100, 105-06, 113-14, 121-22, 127-28, 130-31, 135-6; Kinget Decl., ¶¶ 46, 67, 83.) [redacted]

[redacted]



Notably, Dr. Scandella did not perform an analysis on each unit to determine whether it had fluidics and non fluidics sections separated as required by the claim. Moreover, many of the five modules that Dr. Scandella relied on to establish infringement have additional electronics or electrical components on the same side of the panel member as the fluidics. For example, the single and multi-wavelength UV detectors with conductivity cells that Dr. Scandella referenced (Scandella Decl. ¶¶ 32, 39, 41) also include an LED screen on the same side of the panel member as the fluidics as shown in the figures below. [redacted] The Single Wavelength detector unit has even more electrical components on the same side of the panel member as the fluidics. [redacted]

[redacted] Dr. Scandella admitted that these are both electrical components and Bio-Rad's experts agree. (Gale Decl., ¶¶ 108-10, 168-69; Kinget Decl., ¶¶ 35-38.)

[redacted]

Other Bio-Rad NGC units include additional electronics and electrical components on the user side of the [redacted], alongside the fluidics. For example, the system pump and sample pump include electronic switches on the outside of the unit; [redacted] (Gale Decl., ¶¶ 96-97, 101, 107-11, 115-18, 123-25, 132-33, 137-39; Kinget Decl., ¶¶ 41-47; 59-64; 73-83.)

Dr. Scandella, when confronted with the fact that each of the NGC units he identified as meeting the elements of the claims has electronics on the same side of the panel member as the fluidics, and outside the housing, attempted to distinguish among different types of electronic components. For example, Dr. Scandella attempted to distinguish "major" and "minor" electronics or electrical components, arguing the that the claims of the '718 patent are referring to "major" electronics or electrical components. (Ex. 5, 10/17/2014 Scandella Dep. Tr. at 73:22-75:14.) However, Dr. Scandella admitted that the patent draws no such distinction. (*Id.* ("the

patent doesn't directly address the issue of a minor component of the system").) According to Dr. Scandella, the location of "minor" components such as pressure sensors and temperature sensors is "necessary" for the units to function, and therefore their location is not "an issue" for the patent and they can be external to the housing. (Ex. 5, 10/17/2014 Scandella Dep. Tr. at 75:8-14; 98:14-16.) Dr. Scandella's distinctions are wholly unsupported by the claim language, specification, or prosecution history. Furthermore, even if Dr. Scandella's efforts to distinguish "necessary" electrical components were tenable, which they are not, the LEDs, LED screens, and electronic switches on the Bio-Rad NGC units are not necessary for any of the units to function. (Gale Decl., ¶ 172.) These features are added for the convenience of the user. (*Id.*)

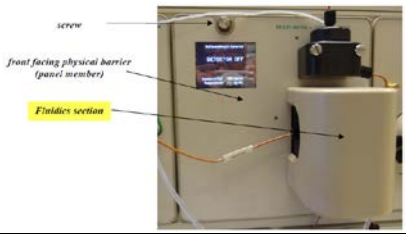
3. The NGC System Lacks a "housing . . . such that said respective fluidics sections are external to the housing and said respective non fluidics sections are internal to the housing"

The NGC systems do not include a housing "wherein the two or more component positions of the liquid handling panel are arranged for attachment of the panel members such that said respective fluidics sections are external to the housing and said respective non fluidics sections are internal to the housing." For essentially the same reasons described above, the NGC systems do not satisfy this element: the NGC units include numerous electronics and electrical components on the exterior of the units, on the user side of the [redacted], outside the system housing. [redacted] (Gale Decl., ¶¶ 75-79, 140-42; Kinget Decl., ¶¶ 55-58.)

D. The Applikon Prior Art Systems Anticipate All Asserted Claims of the '718 Patent

[3] Additionally, the mixer and buffer blender units have fluidics that travel inside the housing. (Gale Decl., ¶¶ 86-88, 101-02.). Dr. Scandella testified that this was interesting and not something he considered in relation to whether it met the claim element. (Ex. 5, 10/17/2014 Scandella Dep. Tr., at 84:3-24.)

To the extent the claims are construed to allow electronics on the same side of the panel member as the fluidics and outside the housing, they are invalid over Applikon's 2040 system ("ADI 2040").[4] The ADI 2040 was on sale in the United States in 1999 and a brochure describing its features and functions was available on the internet and to customers by no later than September 2008. (Koshy Decl. ¶¶ 4, 7.) As demonstrated in Dr. Gale's declaration, the ADI 2040 includes each element of the '718 claims. The ADI 2040 is described as a modular unit, and includes 20 individual modules, each having a panel member separating fluidics and electronics, as shown in Figures below. (Gale Decl., ¶¶ 195-247) The electronics for as many as twenty modules are located on the side of the panel member internal to the system housing, separated from the fluidics. Importantly, the ADI 2040 brochure states that the electronics are sealed from the wet components of the system. ADI 2040 Brochure 3 ("the electronic compartment is sealed from the outside as well as from the wet part of the Analyzer"). For these reasons and as more specifically detailed in Dr. Gale's declaration, the ADI 2040 contains all the elements of the '718 claims and renders them invalid. (Gale Decl., ¶ 192-244.)

		
ADI 2040 Brochure at 4.	ADI 2040 Brochure at 3.	Scandella Dec. Fig. 41.

E. GE's Failure to Disclose Its Own Prior Art Systems to the USPTO Renders the '718 Patent Unenforceable

In addition to the ADI 2040 system, several prior GE systems are invalidating prior art to the '718 patent. (Gale Decl., ¶¶ 245-315) GE's failure to disclose these prior art systems to the

[4] Applikon's 2045 system also discloses each and every element of the claims of the '718 patent, and anticipates and/or renders obvious the claims of the '718 patent for the reasons and as specified in Dr. Gale's Declaration. (Gale. Decl., ¶¶ 195-247.)

USPTO during prosecution of the patent-in-suit likely constituted inequitable conduct that renders the '718 patent unenforceable. *Therasense, Inc. v. Becton, Dickinson and Co*., 649 F.3d 1276 (Fed. Cir. 2011). [redacted]

II. GE Has Failed to Prove Irreparable Harm

In addition to failing to show a likelihood of success on the merits, GE similarly fails to demonstrate irreparable harm. GE points to purported harms that occurred ***prior to*** the issuance of the '718 patent, but fails to provide evidence that GE will suffer any ongoing irreparable harm in the absence of an injunction. *See Novozymes A/S v. Danisco A/S*, 10-CV-251, 2010 WL 3783682, at *3 (W.D. Wis. Sept. 24, 2010) (denying preliminary injunction for failure to show irreparable harm where patent issued the day the suit was filed and plaintiffs incorrectly focused "on 'harm' that occurred before [the patent] was issued in May 2010, when it was perfectly legal for defendants to use [the accused product] to compete with [plaintiff]").

Irreparable harm requires proof that a plaintiff will likely suffer serious and permanent damage to its business, market presence, or reputation during the pendency of the lawsuit if an injunction does not issue. *See Caldwell Manuf. Co. N. Am., LLC v. Amesbury Grp., Inc.*, 2011 WL 3555833, *3 (W.D.N.Y. Aug. 11, 2011); *Kimberly-Clark Worldwide, Inc. v. Tyco Healthcare Group LP*, 635 F. Supp. 2d 870, 880 (E.D. Wis. 2009). To satisfy the causal nexus requirement, a patentee must demonstrate not only that irreparable harm exists, but also that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement. *See Apple v. Samsung*, 695 F.3d at 1374. In particular, the patentee must show "that the infringing feature

drives consumer demand for the accused product." *Id*. at 1375. A plaintiff must also prove that "remedies available at law, such as monetary damages, are inadequate to compensate for that injury." *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

At the preliminary injunction stage, the mere fact that the parties are direct competitors, or that the market is essentially a two player market, is insufficient to establish irreparable harm and actually weighs against preliminary injunctive relief.[5] *See, e.g., Caldwell Mfg. Co. North America, LLC v. Amesbury Group, Inc*., No. 11-CV-6183, 2011 WL 3555833, at*5 (W.D.N.Y. Aug. 11, 2011). In fact, the presence of only two competitors in a given market militates ***against*** issuance of a preliminary injunction. *See id*. at *6. Moreover, in a two player market, monetary damages are more likely to be adequate. *See MMJK, Inc. v. Ultimate Blackjack Tour LLC,* 513 F. Supp. 2d 1150, 1157 (N.D. Cal. 2007) (stating that in a two player market, monetary damages would be sufficient because any lost market share would likely be recoverable). Under these well-established standards, GE has failed to prove irreparable harm.

A. GE Has Failed to Prove That the Alleged Patented Features Drive Consumer Demand for the NGC System

To satisfy the causal nexus requirement, GE must present "evidence that directly ties consumer demand for the [NGC] to its allegedly infringing feature[s]" and that consumers buy the NGC "because it is equipped with the [features] claimed in the ['718] patent." *See id*. at 1375. The causal nexus requirement is not satisfied simply because removing an allegedly infringing component would leave a particular feature, application, or device less valued or inoperable. *See id*. at 1376.

GE has failed to establish a causal connection between the patented features and any lost

[5] The cases GE cites are wholly inapposite in that they involve permanent, rather than preliminary injunctive relief. *See, e.g., Robert Bosch LLC v. Pylon Mfg Corp*., 659 F.3d 1142, 1151 (Fed. Cir. 2011).

sales or other harm resulting from Bio-Rad's sales of the NGC systems. GE has not provided evidence of demand for the claimed benefits of the patented features, identified by GE as modularity and separation of fluidics and non fluidics (electronics) sections. [redacted]

B. GE Has Failed to Prove Irreparable Harm Through Lost Sales

As Dr. Kearl sets out in detail in the accompanying declaration, GE has not shown that the NGC system has had any meaningful impact on GE sales of AKTA Avant or Pure. (Kearl Decl., ¶¶ 31-35.) [redacted]

[redacted]

C. GE Has Failed to Prove Irreparable Harm Through Price Erosion

GE's speculative and unsupported claims of price erosion are similarly insufficient to prove irreparable harm, especially when the alleged harms occurred ***prior*** to the issuance of the patent. *See Novozymes*, 2010 WL 3783682, at *3; *see also Am. Beverage Corp. v. Diageo N. Am., Inc.*, 936 F. Supp. 2d 555, 614 (W.D. Pa. 2013) ("prospective equitable relief cannot remedy past harms"); *Trudeau v. Bockstein*, No. 05-cv-1019, 2008 WL 541158 at *6 n.8 (N.D.N.Y. Feb. 25, 2008) ("[I]rreparable harm cannot be established by reference to past injury").

In addition, as Dr. Kearl discusses in his declaration, the available evidence suggests that the amount of price erosion that GE is likely to experience is modest or none. (Kearl Decl., ¶¶ 36-38.) [redacted]

[redacted]

[redacted] Furthermore, to the extent that the entire price decline occurred before GE's patent issued, GE would not be entitled to be compensated for damages resulting from that decline, and may not use any such decline as the basis for a claim of irreparable harm to support an entitlement to injunctive relief. *See Novozymes*, 2010 WL 3783682 at *3 (rejecting argument that price erosion was irreparable where patent issued the day the suit was filed and reasoning that "because defendants have already been selling the accused products at a lower price for 'a significant period,' any damage on that front is likely already done").

D. GE Has Failed to Prove Irreparable Harm Through Loss of "First Mover Advantage" and Goodwill

GE also claims that absent an injunction, it will suffer a loss of first mover advantage and goodwill. As Dr. Kearl discusses in his declaration, this outcome appears to be very unlikely. The terms "first mover advantage" and "goodwill" are vague, and GE provides no guidance on the specific types of harm it believes it will suffer in this regard. (Kearl Decl., ¶ 39.)

Whatever GE means, however, it is unlikely that this harm will occur absent an injunction. As noted above, GE and Bio-Rad have competed for many years in the market for protein separation systems, and whatever reputation and goodwill GE has is largely the result from this history. (Kearl Decl., ¶ 40.) As a consequence, if these innovations were going to give GE a first mover advantage, they would have already done so well before Bio-Rad entered the market with its accused products. (Kearl Decl., ¶ 40.) Moreover, to the degree that the

introduction of the accused Bio-Rad products would diminish the GE first mover advantage and goodwill, that damage is already done and is not affected by an injunction at this point. (Kearl Decl., ¶ 41.) Bio-Rad introduced its accused products in 2013, more than a year before the GE patent was issued. Thus, whatever harm to GE is occasioned by the introduction of the accused Bio-Rad products is not harm that resulted from patent infringement, and is not harm that can now be undone by an injunction. (Kearl Decl., ¶ 41.) *See Novozymes*, 2010 WL 3783682, at *3.

[redacted] *See Z-Man Fishing Products, Inc. v. Renosky*, 790 F. Supp. 2d 418, 423 (D.S.C. 2011) (no irreparable harm where patentee had not offered any "evidence of lost goodwill"); *Apple, Inc. v. Samsung Electronics Co.*, No. 11-01846, 2011 WL 7036077, at *18 (N.D. Cal. Dec. 2, 2011) (rejecting conclusory expert statements and requiring "concrete evidence" that Samsung's alleged infringement injured Apple's "reputation for innovation".)

E. GE Has Failed to Prove the Inadequacy of Monetary Damages

To prove irreparable harm, GE must show that any injury it identifies cannot be compensated by money damages. *eBay*, 547 U.S. at 391; *see also Automated Merch.*, 357 F. Appx. at 301 (burden is on patentee to show that harms it has identified cannot be remedied by

monetary damages). There is no presumption that money damages would be inadequate. *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc*., 49 F.3d 1551, 1557 (Fed. Cir. 1995). GE has failed to show that its harm is not compensable through monetary damages. *Nutrition 21 v. United States*, 930 F.2d 867, at 872 (Fed. Cir. 1991). As Dr. Kearl discusses in detail in his declaration, any harm to GE would be readily quantifiable. (Kearl Decl., ¶¶ 44-55.) GE claims that it competes directly with Bio-Rad in a two-player market, and that each sale of a Bio-Rad accused product represents a lost sale to GE. To the degree that GE is correct, estimation of the number of lost sales is a trivial exercise. Moreover, even if GE is correct that each sale of an accused Bio-Rad product is a sale lost to GE, quantification of the number of lost sales should be straightforward. *See Automated Merch. Sys., Inc. v. Crane Co.*, 357 Fed. App'x. 297, 302 (Fed. Cir. 2009) ("Lost sales (without more) are presumed to be compensable through damages, so they do not require injunctive relief."); *Abbott Labs. v. Andrx Pharms., Inc*., 452 F.3d 1331, 1348 (Fed. Cir. 2006) (same); *Travel Tags, Inc. v. UV Color, Inc*., 690 F. Supp. 2d 785, 801 (D. Minn. 2010) ("lost sales" are "generally quantifiable and not remediable through preliminary injunctive relief").

GE and Bio-Rad have competed with each other in the sale of protein purification systems for many years. Thus, a damages expert will have a rich "pre-infringement" history of competition between the companies, which should make the estimation of lost sales a straightforward and precise exercise. (Kearl Decl., ¶ 46.) [redacted] (Kearl Decl., ¶ 47.) [redacted]

[redacted]. Dr. Kearl, in his declaration, sets out further support for his opinion that any damages GE has suffered would be readily quantifiable. (Kearl Decl., ¶¶ 44-55.)

III. The Balance of Hardships Weighs in Bio-Rad's Favor

"An injunction should not be granted if its impact on the enjoined party would be more severe than the injury the moving party would suffer if it is not granted." *Litton Sys. Inc. v. Sundstrand Corp.*, 750 F.2d 952, 959 (Fed. Cir. 1984). "The hardship on a preliminarily enjoined manufacturer who must withdraw its product from the market before trial can be devastating." *Illinois Tool Works*, 906 F.2d at 683. Here, the balance of hardships favors Bio-Rad.

As shown above, GE has no evidence linking its claimed losses to the accused features of the NGC System. Absent that link, there is no basis to conclude that GE's harm results from Bio-Rad's alleged infringement rather than from lawful competition from the NGC systems and other products. [redacted] *See Techradium, Inc. v. Blackboard Connect Inc.*, 2009 WL 1152985, *7 (E.D. Tex. Apr. 29, 2009).

IV. An Injunction Will Not Serve the Public Interest

GE argues that the public interest in enforcing valid patents will be served by an injunction. (Opening Brief at p. 21.) However, merely owning a valid patent is not sufficient to justify an injunction; such a rule "would render much of the four-part injunction analysis unnecessary." *Kimberly-Clark Worldwide*, 635 F. Supp. 2d at 880. GE has not shown any other public interest that would be served by an injunction. The public also has an interest in promoting competition, particularly in areas such as the products at issue here, that can be used

[6] Notably, GE incorrectly describes one of the cases it relies on for the proposition that its investments in developing the new AKTA systems weigh in favor of preliminary injunctive relief. *See Med. Econ. Co. v. Prescribing Reference, Inc.*, 294 F. Supp. 2d 456, 462 (S.D.N.Y. 2003) (***denying*** preliminary injunction on the grounds that the ***non-moving party*** had invested significant resources in the accused product).

in research to develop cures and diagnostics for serious diseases. *See Yamashita v. Wilbur-Ellis Co*., 2006 WL 1320470, at *8 (N.D. Cal. May 15, 2006) (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)) ("[T]he Supreme Court . . . made clear long ago that 'the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain'").

Removing the accused products from the market based on alleged infringement of non-core features would fail to serve the public's interest in enjoying the benefits of competition, particularly in light of GE's failure to make a strong showing of likely success on the merits of its claim. *See American Cyanamid Co. v. United States Surgical Corp*., 833 F. Supp. 92, 134 (D. Conn. 1992) (where "the Plaintiff has not made a strong showing that it will succeed on the merits, the balance between the rights granted by the patent system and free competition should be struck in favor of competition" (internal quotation omitted)). In addition, if GE's argument that the relevant market is essentially a two player market is accepted, the public interest weighs still more heavily against issuance of a preliminary injunction. *See, e.g., Cummins-Allison Corp. v. Glory Ltd*., No. 02-CV-7008, 2003 WL 355470, at *52 (N.D. Ill. Feb. 12, 2003).

CONCLUSION

For the forgoing reasons, GE's Motion for Preliminary Injunction should be denied.

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Respectfully submitted,

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